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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,667	01/14/2004	Anthony John Kinney	BB1071 US DIV2	7292
23906	7590	09/21/2007	EXAMINER	
E I DU PONT DE NEMOURS AND COMPANY LEGAL PATENT RECORDS CENTER BARLEY MILL PLAZA 25/1128 4417 LANCASTER PIKE WILMINGTON, DE 19805			KUMAR, VINOD	
			ART UNIT	PAPER NUMBER
			1638	
			NOTIFICATION DATE	DELIVERY MODE
			09/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-Legal.PRC@usa.dupont.com

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/757,667	KINNEY ET AL.
	Examiner Vinod Kumar	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 May 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 22-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 22-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 11/24/2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/10/2007</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

***DETAILED ACTION***

***Status of objections and rejections***

1. Office acknowledges the receipt of Applicant's response filed on May 10, 2007.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 22-24 are pending. Claims 22-24 are examined on merits in the instant Office action. All previous claim objections and rejections not set forth below have been withdrawn in view of claim amendments. This action is made FINAL.

***Specification***

2. Objection to the specification is maintained because brief descriptions to drawings do not identify all the labels in Figures 5 and 7.

Appropriate action/corrections are required.

***Claim Objections***

3. Claims 22-24 are objected to because of the following informalities:
    - In claim 24, line 13, change "plant" before "compared" with --seeds--.
    - In claim 24, line 14, change "a non-transgenic soybean" with --non-transgenic soybean seeds not comprising the chimeric gene--.
- Appropriate action/corrections are required.

***Double Patenting***

4. Claims 22-24 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-9, 12, and 14-20 of U.S. Patent No. 6,703,544 ('544) and in view of Kinney et al. (U.S. Patent No. 6,703,544, issued March 9, 2004) for the reasons of record stated in the Office action mailed on January 10, 2007. Applicants traverse the rejection in the paper filed on May 10, 2007.

Applicants argue that the instant application and the application on which the '544 patent issued were both divisional applications filed in response to a restriction requirement issued by the Office. Applicants further argue that rejection of claims 22-24 based on the ground of nonstatutory obviousness-type double patenting falls within the prohibition of double patenting rejections under 35 U.S.C. 121. Applicants cite MPEP 804.01 for prohibition of double patenting rejections under 35 U.S.C. 121 to support their arguments (response, page 6, lines 16 through the end of 1<sup>st</sup> paragraph of page 7).

Applicant's arguments were fully considered but were not found to be persuasive. Applicant's attention is specifically drawn to MPEP 804.01[R]3, part (B) which says:

The claims of the different applications or patents are not consonant with the restriction requirement made by the examiner, since the claims have been changed in material respects from the claims at the time the requirement was made. For example, the divisional application filed includes additional claims not consonant in scope to the original claims subject to restriction in the parent. Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 19 USPQ2d 1241 (Fed. Cir. 1991) and Gerber Garment Technology, Inc. v. Lectra Systems, Inc., 916 F.2d 683, 16 USPQ2d 1436 (Fed. Cir. 1990). In order for consonance to exist, the line of demarcation between the independent and distinct inventions identified by the examiner in the requirement for restriction must be maintained. 916 F.2d at 688, 16 USPQ2d at 1440.

In the instant case, the instant claims are not consonant in scope to the original claims subject to restriction in the parent application. The claims of instant divisional application have been changed in material from the claims at the time restriction was made in the parent application. Accordingly, the rejection is maintained.

5. Claims 22-24 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,362,399 ('399) and in view of Kinney et al. (U.S. Patent No. 6,362,399, issued March 26, 2002) for the reasons of record stated in the Office action mailed on January 10, 2007. Applicant's traversal filed in the paper of May 10, 2007 did not provide separate arguments for this rejection. Accordingly, the rejection is maintained for the reasons as discussed above.

***Claim Rejections - 35 USC § 112***

6. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "sufficient in length" which is confusing since metes and bounds of the recitation "sufficient in length" are unclear as it is not defined.

In the paper filed on May 10, 2007, Applicants argue that support for the recitation can be found on pages 9, 13 and 14.

Applicant's arguments were fully considered but were not found to be persuasive.

The cited pages do not define the term "sufficient in length". It is thus maintained that metes and bounds of the recitation are unclear.

7. Claims 22-24 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a food prepared from soybean seeds having reduced quantity of glycinin and/or  $\beta$ -conglycinin, wherein said seeds are prepared by a method comprising antisense or sense suppression of endogenous seed glycinin and/or  $\beta$ -conglycinin gene expression, comprising transformation of soybean seeds with a chimeric gene which comprises a nucleic acid fragment derived from soybean glycinin or  $\beta$ -conglycinin coding sequence, does not reasonably provide enablement for reducing the levels of (a) soybean glycinin or  $\beta$ -conglycinin seed storage proteins (b) any soybean seed storage protein, comprising transformation of soybean seed with a chimeric gene which comprises a nucleic acid fragment derived from any soybean seed storage protein coding region. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for the reasons of record stated in the Office action mailed on January 10, 2007. Applicants traverse the rejection in the paper filed on May 10, 2007.

Applicants argue that Examples 1-3 of the specification provide enough guidance to one skilled in the art to reduce expression of the conglycinin seed storage proteins in a transgenic soybean seed using antisense or sense based gene suppression approaches. Applicants also argue that Example 4 provides guidance in suppressing

expression of glycinins in soybean seeds using similar approaches. Applicants further argue that the desired gene suppression can be achieved whether or not a full-length sequence is used or whether or not there is some sequence variation. Applicants cite U.S. Patent No. 5,231,020 to support their arguments (response, pages 8-10).

Applicant's arguments were fully considered but were not found to be persuasive. Example 1 of the specification clearly indicates unpredictability of reducing expression of endogenous seed storage proteins in a plant seed cell using sense suppression based approach. It is noted that Table 1 clearly indicates or suggests the following: (a) majority of transgenic embryos failed to exhibit reduced levels of all conglycinin subunits, and (b) expression of an unrelated gene delta-12 desaturase in one transgenic embryo. These unpredictable results further conform with the teachings of Bruening which clearly suggests that the occurrence of gene silencing by sense suppression may be the unexpected outcome, and such transgenic lines may not hold to character when propagated by seed.

Examples 2 and 3 of the specification do not suggest that promoter region of  $\beta$ -conglycinin was capable of suppressing expression of one or more class of soybean seed storage proteins, or at least two soybean seed storage protein genes (other than c glycinins) as encompassed by the breadth of claims 22 and 23, respectively.

While Example 4 of the specification provides guidance on making cosuppression constructs containing the cDNAs corresponding to the group I cDNA of Glycinin and the group II cDNA of Glycinin linked each in sense direction to the  $\beta$ -conglycinin promoter, however, Example 4 fails to address the core issue of reducing

the expression levels of glycinin,  $\beta$ -conglycinin and other seed storage proteins in a soybean seed by transforming said seed with a construct comprising an antisense or sense sequence of glycinin or  $\beta$ -conglycinin. It is noted that no transgenic embryos with reduced levels of soybean seed storage proteins were produced in Example 4.

As discussed in the previous Office action, antisense suppression of gene expression is highly unpredictable (see page 12, 1<sup>st</sup> paragraph of Office action mailed on 01/10/2007). The teachings of Elomma et al. or Colliver et al. clearly suggest that success of gene suppression of a target gene depends on the % identity between the sequence of the antisense construct and the target gene sequence. In view of significant sequence differences between different soybean seed storage proteins (target genes) and the promoter region of  $\beta$ -conglycinin, the promoter region (transcribed part) of  $\beta$ -conglycinin would be unable to down-regulate gene expression of any seed-storage protein.

It is noted that Applicant's cited art (US Patent No. 5, 231, 020) fails to address the issue of suppressing expression of non-homologous seed storage protein gene sequences (target sequences) by the instant cosuppression construct comprising a sense or antisense sequence, which is significantly unrelated to said target sequences.

In the absence of guidance and unpredictability of the related art as discussed above, it is maintained that undue experimentation would have been required by a skilled artisan at the time the claimed invention was made to determine how to use sense or antisense cosuppression based approach in reducing the levels of any soybean seed storage protein using a nucleic acid fragment encoding all or a portion of

any soybean seed storage protein. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, it is maintained that undue experimentation would have been required by one skilled in the art at the time the claimed invention was made to make and use the claimed invention. Therefore, it is maintained that the claims are not commensurate in scope with the teachings of the specification.

8. Claims 22-23 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in the Office action mailed on January 10, 2007. In the response filed on May 10, 2007, Applicants did not address issues related to written description rejection as discussed on pages 15-16 of Office action mailed on January 10, 2007. Applicants are reminded that while some of the issues in the enablement and written description rejections are similar, the two rejections are distinct and Applicants should have addressed written description related issues separately. Accordingly, it is maintained that there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. Accordingly, the rejection is maintained.

9. Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 24 recite "sufficient in length" which introduces NEW MATTER into amended claims. The specification does not provide written description support for the nucleic acid fragment encoding a portion of a soybean seed storage protein which is "sufficient in length" to reduce the amount of at least one of soybean seed storage protein. This does not comply with written description requirements.

#### ***Claim Rejections - 35 USC § 102 & 103***

10. Claims 22-24 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Trueblood et al. (US Patent No. 4,267,118, issued on May 12, 1981) for the reasons of record stated in the Office action mailed on January 10, 2007. Applicants traverse the rejection in the paper filed on May 10, 2007.

Applicants argue that page 2, lines 22-24 of the instant specification describes that the food which constitutes the subject matter of the instant invention is directed to protein concentrates, isolates, and textured protein products, not soybean oil obtained from seeds containing reduced levels of soybean seed storage proteins (response, page 11, lines 17-31).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., food which constitutes protein concentrates, isolates, and textured protein products derived from soybean seeds which is transformed with a suppression construct to down-regulate endogenous seed storage proteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is maintained that the instantly claimed food has the same structural limitations as that taught by the reference. Soybean oil as a food obtained from the claimed method appears to be identical to the soybean oil of the prior art. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) which teaches that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Accordingly, the rejection is maintained.

### ***Conclusions***

11. Claims 22-24 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

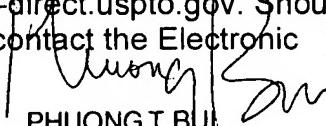
A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is set to expire within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### *Contact Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-5444. The examiner can normally be reached on 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
PHUONG T. BUI  
PRIMARY EXAMINER